K110716

EVERYWAY EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Peishen Rd, Shen Keng Hsiang, Taipei Hsien, Taiwan,

OCT 18 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 at February 28, 2011.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:

   Establishment:EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address: 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Registration Number: 9616877
   Operations: Manufacturer

   Owner/Operator:EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address : 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Contact Person: Robert Tu
   Phone : 886-2-2662-0038
   Fax No: 886-2-2664-5566
   e-mail : tu922@ms35.hinet.net

2. Name of the Device:
   Everyway Low Back Pain Relief System, model EV-820.

3. Information of the 510(k) Cleared Device (Predicate Device):
   Gemore Low Back Pain Relief System, model GM310PP(K060222).

4. Classification Information:
   Trade/Device Name: Everyway Low Back Pain Relief System, model EV-820.
   Regulation Number: 21 CFR 882.5890
   Regulation Name: Transcutaneous Nerve Stimulator
   Regulatory Class: II
   Product Code: NUH

5. Device Description:

   The Everyway Low Back Pain Relief System, models EV-820 is a non-invasive devices which are intended for over the counter use in temporary relief of pain associated with sore and aching muscles in the lower back due to stain from exercise or normal household and work activities.

   The devices contain the following main parts: TENS stimulation unit which was designed to generate 8 preprogram modes of output stimulation pulse, Support Belt, Self-adhesive pads,

and Snap Cable.

With the combination of the main device parts, the device can be worn on the low back part of user so as to place the stimulation pads on the treatment location of low back for over the counter use without prescription in temporary relief of pain associated with sore and aching muscles in the lower back.

6. Intended Use:

The Everyway Low Back Pain Relief System, model EV-820 is indicated for over the counter use in the temporary relief of pain associated with sore and aching muscles in the low back due to stain from exercise or normal household and work activities.

7. Comparison to the 510(k) Cleared Device (Predicate Device):

The Everyway Low Back Pain Relief System, model EV-820 is substantially equivalent to the Gemore Low Back Pain Relief System, model GM310PP(K060222) without any significant difference in main technological and operational feature.

8. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of EV-820 are as the followings:
   1> Performance Compliance Test according to ANSI/AAMI NS4 conducted by manufacturer
   2> Usability Study Report according to IEC 60601-1-6 conducted by manufacturer.
   3> Electrical Compliance Test according to IEC 60601-1 by accredited laboratory.
   4> EMC Compliance Test according to IEC 60601-1-2 by accredited laboratory.
   5> Biocompatibility Test for the support belt and stimulation electrode according to ISO 10993-5 & ISO 10993-10 by accredited laboratory.

9. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:
   No particular Clinical Test was conducted for Everyway Low Back Pain Relief System, model EV-820.

10. Conclusions
    The Everyway Low Back Pain Relief System, model EV-820, has the same intended use and technological characteristics as the cleared device of Gemore Low Back Pain Relief System, model GM310PP(K060222). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted model could maintain the same safety and effectiveness as that of cleared device.

    In the other words, Everyway Low Back Pain Relief System, model EV-820 is substantial equivalent with the Gemore Low Back Pain Relief System, model GM310PP(K060222).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2011

Everyway Medical Instruments Co., Ltd.
c/o Mr. Robert Tu
President and Operator Owner
3 Fl., No. 5, Lane 155, Sec. 3
Peishen Rd., Shenkeng Hsiang
Taipei Hsien 222
Taiwan

Re: K110716
Trade/Device Name: Everyway Low Back Pain Relief System (Model EV-820)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: October 4, 2011
Received: October 5, 2011

Dear Mr. Tu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EVERYWAY EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Peishen Rd, Shen Keng Hsiang, Taipei Hsien, Taiwan,

Indications For Use

510(k) Number (if known): K110716 .

Device Name: **Everyway Low Back Pain Relief System, model EV-820.**

Indications For Use:

The Everyway Low Back Pain Relief System, model EV-820 is indicated for over the counter use in the temporary relief of pain associated with sore and aching muscles in the low back due to strain from exercise or normal household and work activities

Prescription Use _____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110716